REPORT DOCUMENTATION PAGE

Form Approved OMB No. 0704-0188

1. AGENCY USE ONLY *(Leave blank)*	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	8.Aug.06	MAJOR REPORT

4. TITLE AND SUBTITLE
THE SAFETY OF DESSICATED BARALYME IN THE NARKOMED-M ANESTHESIA MACHINE: THE EFFECT OF ISOFLURANE AND SEVOFLURANE AT LOW AND HIGH FLOW O2 ON ABSORBENT

5. FUNDING NUMBERS

6. AUTHOR(S)
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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
USUHS - WRIGHT PATTERSON AFB

8. PERFORMING ORGANIZATION REPORT NUMBER
CI04-1855

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
THE DEPARTMENT OF THE AIR FORCE
AFIT/CIA, BLDG 125
2950 P STREET
WPAFB OH 45433

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION AVAILABILITY STATEMENT
Unlimited distribution
In Accordance With AFI 35-205/AFIT Sup 1

12b. DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200 words)*

14. SUBJECT TERMS

15. NUMBER OF PAGES
24

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT

Pages:24
Words:3,994
Tables & Figures: 3
Photos: 0
References:16
Contact: Capt Glenn
Guarantor: LCDR Stone

The Safety Of Desiccated Baralyme® In The Narkomed-M Anesthesia Machine: The Effect of Isoflurane and Sevoflurane at Low And High Flow O2 on Absorbent Temperature

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American Association of Nurse Anesthetists Annual Conference, Cleveland, OH Aug 5-9, 2006

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Abstract

Objective: To determine the clinical safety of using partially desiccated Baralyme® in a Narkomed-M anesthesia machine by measuring the maximum temperature within the absorbent and time to maximum temperature under standard OR conditions.

Methods: Four experimental conditions were set using sevoflurane (experiment) vs. isoflurane (control) at low (3L) vs. high (5L) O_2 flows. Baralyme® was partially desiccated by 12 hours high-flow air to 10.8% moisture.

Results: Twenty three trials showed no significant interaction of Agent and Liter-flow for temperature ($p=.896$) or time ($p=.668$), nor was there a significant main effect for Agent for temperature ($p=.230$) or time ($p=.863$). Three Liter-flow showed a consistently higher temperature than the 5L flow overall (44.5°C vs. 41.5°C, $p<.001$), and for both Isoflurane, (44.8°C vs. 41.8°C, $p=.001$) and Sevoflurane, (44.2°C vs. 41.1°C, $p=.006$).

Conclusion: Partially desiccated Baralyme® showed no clinically significant temperature increases and appears to be safe to use in a Narkomed-M under normal clinical conditions.

Introduction

The purpose of this experimental study design is to determine if partially dehydrated Baralyme®, a carbon dioxide (CO_2) absorber, will cause extreme heat when exposed to Svoflurane.. Sevoflurane is an inhaled anesthetic agent used in general anesthesia to produce unconsciousness, amnesia, analgesia and a degree of muscle relaxation for the surgical patient (1). Until recently, Baralyme® was used in the dual carbon dioxide absorbent canisters of most anesthesia machines. The anesthesia machine utilized in this study is the Narkomed M. It is a unique machine because it only has a single carbon dioxide canister and Baralyme® is used in the carbon dioxide canister. The Narkomed M is lightweight, portable, and is currently used by the United States military anesthesia providers in the deployed setting.

Background

The contemporary anesthesia machine used in the United States military health care system is a fixed system. The components of the contemporary anesthesia machine consist of a pressure system, vaporizers, and a ventilator. Each component connects to a breathing circle system. Compressed medical grade oxygen or air, at a high pressure (50 pounds per square inch) drives the anesthesia machine (2).

The amount of oxygen delivered to the anesthetized patient is controlled by flow meters that determine the liters per minute a patient will receive and the percentage of oxygen delivered. Once the flow and percentage of oxygen is determined, the oxygen/air is mixed with the anesthetic gases in the vaporizer. The vaporizer delivers a measurable amount of volatile anesthetic into the anesthesia machine and out the common gas outlet into the breathing circle system that is connected to the patient (2).

Each anesthetic agent has its' own specific vaporizer to ensure accurate concentrations are delivered to the patient. The contemporary anesthesia machine is able to accommodate three different vaporizers or three different anesthetic agents. A safety mechanism is built into the anesthesia machine preventing the delivery of more than one anesthetic agent at a time into the breathing circle system.

The ventilator is part of the anesthesia machine and controls the breathing circle system. The ventilator delivers a measurable amount of volume to the patient at an adjustable rate (2). The breathing circle system has a dual canister carbon dioxide absorber that removes expired carbon dioxide from the patient. The presence of the carbon dioxide absorber allows the recycling of the anesthetic agent and oxygen that are delivered into the breathing system. The

removal of the carbon dioxide from the breathing circle system allows the anesthesia provider to use lower flows of oxygen and conserve the amount of anesthetic agent used (2).

There are a few commercially available carbon dioxide absorbers: soda lime, barium hydroxide lime (Baralyme®), and Amsorb®. The absorbents granules are small, irregular shaped to increase surface area and are tightly packed (1.3 kilograms) into a canister. The two canisters are placed on top of each other in a housing unit within the breathing circle system. The fundamental principle of each carbon dioxide absorber is to remove expired carbon dioxide from the patient. The end products of each system are similar, differing mainly in the amount of calcium hydroxide and heat that are produced.. After some period of use, the granules can no longer absorb carbon dioxide and are said to be "exhausted". As the granules become exhausted a chemical reaction occurs with ethyl violet within the granules and they turn purple. (2).

Many components of contemporary anesthesia machines have been integrated into a portable anesthesia machine manufactured by Narkomed. The Narkomed M anesthesia machine utilizes a single canister of carbon dioxide and only one volatile agent can be connected to the machine at any given time.. The United States military uses the Narkomed M anesthesia machine in it's deployed locations because it provides the integration of safety features with the required portability.

In recent years, professional anesthesia journals have reported several accounts of fires and explosions in the carbon dioxide absorber canister and the anesthesia breathing circuits when desiccated Baralyme® and Sevoflurane were used (4,5,6,7). This presents a major patient safety concern.

In January 2004, the Food and Drug Administration (8) released a caution letter regarding the risk of fire during the exposure of desiccated Baralyme to sevolurane.®. In October 2004, , Allied Healthcare Products Inc., the manufacturer of Baralyme®, stopped production because of the safety concerns associated with the recent findings (9). However, the United States military has a ready reserve supply of Baralyme®, and the potential exists to encounter Baralyme® in the deployed setting.

The current review of literature concerning the phenomena of conflagration when evoflurane was exposed to desiccated Baralyme® revealed limited primary sources. Currently, two research studies address the issue of extreme heat production.

The first study by Laster et al. (2004) examined the effects of desiccated Baralyme® when using the inhaled anesthetics Desflurane, isoflurane, or sevoflurane. Conflagration occurred two hours into the experiment. Significant findings in this study suggested sevoflurane undergoes the largest degradation when exposed to desiccated Baralyme®. The researchers proposed that sevoflurane degradation is enhanced by the lack of potassium hydroxide, resulting in the increased temperature in the Baralyme®. Isoflurane temperature readings remained low and exhibited little variability.

Holak et al. (2003) examined the effects of temperature and the rate at which carbon monoxide is produced in the presence of the desiccated Baralyme® absorbent sample. Sevoflurane was chosen because it has the highest degradation rate among the inhaled

anesthetics and is the least studied. The results of this study suggest that carbon monoxide increases in the presence of desiccated Baralyme® and sevoflurane.

Of note, all research to date, on the reaction to Baralyme to inhaled anesthetic agents, had been performed using standard ,double canister absorbers. The purpose of this research was to examine the effects of this reaction utilizing the single canister Narkomed M field anesthesia machine.

heoretical Frame Work

The framework utilized in this study is the fire tetrahedron. The fire tetrahedron is used to illustrate the components needed to produce a fire. The fire tetrahedron model provides a rational scientific explanation of the components needed to produce combustion and fire. A tetrahedron is a three dimensional triangle, with four sides and a base. The four elements of the fire tetrahedron are oxygen, heat, fuel, and a chemical reaction. All correspond to a plane in the three dimensional structure. In order for combustion to take place, all four elements must exist in the

correct proportions, which are represented by the equal sides of the tetrahedron If any one element is missing or the proportions are not correct, combustion will not occur (12).

Volatile anesthetic agents react with and are degraded by carbon dioxide absorbent materials that contain strong monovalent bases. The volatile agent sevoflurane contains mono-fluoromethyl ether, a chemical component that makes it more susceptible to degradation. Sevoflurane degrades to compound A and the heat released from the degradation process adds to further degradation, as well as the production of new compounds to include formic acid, methanol, and formaldehyde. In the case of Baralyme® and sevoflurane, these chemical reactions can become extremely exothermic under the appropriate conditions as might exist in hospital environment (11).

The fire tetrahedron model illustrates the contributing factors for conflagration to occur: An oxidizing source, oxygen that is used in an anesthesia machine circuit. A fuel source, carbon molecules caused by the degraded carbon dioxide absorbent and the volatile anesthetic agent sevoflurane. Heat is produced by the chemical reactions between desiccated Baralyme® and sevoflurane in the carbon dioxide canister. The continual degradation of sevoflurane in desiccated Baralyme® causing the ongoing loss of moisture and the production of extreme heat.

Problem Statement

Conditions for partially drying (desiccating) the Baralyme® and use of sevoflurane are likely to be experienced in hospital deployed environments. Limited supplies and repeated use of absorbent are commonplace, thus a potential safety hazard may exist. The purpose of this research is to investigate the interactions between partially desiccated Baralyme® and sevoflurane in the Narkomed-M, a single CO_2 absorbent canister anesthesia machine. The following questions are explored:

1. When using a three-liter flow, will isoflurane or sevoflurane produce a higher maximum temperature?
2. When using a three-liter flow, will isoflurane or sevoflurane take more time to reach maximum temperature?
3. When using sevoflurane, will a three or five liter flow produce a higher maximum temperature?
4. When using sevoflurane, will a three or five liter flow take more time to reach maximum temperature?
5. Will there be a significant change in the maximum temperature between the six trials?
6. Will there be a significant change in the time to reach maximum temperature between the six trails?
7. Will one of the four temperature probes register the highest maximum temperature a larger proportion of the time than the others?

Methods and Materials

The methods for this study were to model the study by Laster, Roth, and Eger (2004). A glass flask was filled with a total of 5.5 kg (four single use samples) of standard commercially available Baralyme® brand barium hydroxide lime carbon dioxide (CO_2) absorbent. A rubber stopper was placed over the opening with two tubes connected, one for entry and one for exit of drying gas. The "drying" gas used was medical grade compressed air. The flow was 10 liters/minute for 12 hours. The purpose was not to completely desiccate the absorbent, but to

partially desiccate it, mimicking environmental conditions seen in arid climates during a deployed military setting.

The moisture content of Baralyme® reported in the material safety data sheet is 11 percent (12). The total sample was reweighed after the 12 hour drying process and then divided into four equal portions. The divided samples were weighed at the start of each new test trial. The moisture content lost from the experiments was reported as a percentage lost by change in net weight. While awaiting placement into the Narkomed-M for conduction of the experiment, the partially desiccated Baralyme® was stored in an airtight flask to prevent introduction of atmospheric humidity.

The four equal samples were assigned to a trial group. Samples 1 and 2 were used for sevoflurane at 3 and 5 liters flow, respectively. Samples 3 and 4 were used for isoflurane, at 3 and 5 liters flow respectively. The same Baralyme® sample was used in more than one test trial, but exposure to volatile agent was limited to either sevoflurane or isoflurane, not both. The same sample was not used for more than one trial consecutively. Sufficient time was afforded to allow the sample to return to room temperature prior to retesting.

The total sample of the partially desiccated Baralyme® was divided into four equal samples. The Narkomed-M's single canister was filled with one of these samples. As in the study by Laster, Roth, and Eger, (2004) four temperature probes were placed. The "bottom" probe was placed one centimeter above the bottom of the absorbent in the center of the canister. The "top" probe was placed one centimeter under the surface of the absorbent in the middle of the canister. The "middle" probe was placed in the absolute center of the absorbent canister. The "outer" probe was placed one centimeter from the outer edge of the wall of the canister. A US Air Force

thermodynamics lab provided the temperature probes, measuring device, and the computerized recording device.

An anesthesia circuit was assembled to mimic the delivery anesthesia, which as monitor end tidal CO_2 and respiratory gas monitoring. Both end tidal CO_2 and the respiratory gas monitor provided accurate measurement of the amount of CO_2 and the percent of volatile anesthetic agent present. A three-liter reservoir bag served as a simulated patient lung. A 61 centimeter noncompliant polyvinyl tube introduced CO_2 into the "lung" to simulate metabolic respiratory gases of a 70 kilogram human. The goal was to maintain an end tidal CO_2 level of 30 to 35 millimeters of mercury (13). This model was used in each of the four sample groups.
All experiments were repeated six times at 1.3 minimum alveolar concentrations (MAC). MAC is defined as the minimum alveolar concentration of an anesthetic required to eliminate movement to noxious stimuli in 95% of subjects (14). Trial group 1 consisted of sevoflurane at 1.3 MAC (2.3% delivery concentration) at three liters fresh gas flow. Trial group 2 consisted of sevoflurane at 1.3 MAC (2.3% delivery concentration) at five liters fresh gas flow. Isoflurane was used as the control group in which sevoflurane was compared to in each trial and between each group. Trial group 3 will consisted of isoflurane at 1.3 MAC (1.4% delivery concentration) at three liters fresh gas flow. Trial group 4 comprised of isoflurane at 1.3 MAC (1.4% delivery concentration) at five liters fresh gas flow measured by end tidal agent (ET_{AGT}).The ventilator of the Narkomed-M was set to deliver a minute ventilation of 9.9 liters per minute, with 660 milliliters tidal volume at 15 breaths per minute.

Temperatures were recorded at one-minute intervals for each of the four temperature probes. A temperature reading of 100° C will be the maximum allowed temperature before

stopping the trial in order to prevent damage to the Narkomed-M anesthesia machine. Each trial was conducted for 120 minutes.

Results

Data was analyzed using SPSS for Windows, version 12.01 (SPSS Inc. Chicago IL). Research questions 1-4 were analyzed by Multivariate Analysis of Variance (MANOVA) to assess the overall differences in mean maximum temperature and mean time to maximum temperature at the two different liter flows (3L and 5L) and for the two separate agents (sevoflurane and isoflurane).

Data was first assessed to assure that the assumptions of MANOVA were met prior to data analysis. Data met the assumptions of linearity via scatterplot analysis, and of multicollinearity by correlation analysis ($r<.80$, $r = -.55$). Only one trial was found to be problematic. Trial 7 was a univariate outlier with a mean >4 SD's above the overall mean as well as a multivariate outlier with a Mahalanobis distance of 18.897, well above the critical value of 13.82. In addition visual analysis of the case showed that it displayed a pattern of temperature rise different from all of the other trials with a sharp initial spike to an extreme temperature. This pattern was indicative of CO_2 not being flushed through the canister due to either operator error or equipment malfunction. Because of these issues trial 7 was deemed erroneous and was dropped from all further analysis and only the remaining 23 trials were included in the analysis. The data met the final assumption of Homogeneity of the Variance Covariance Matrix, with Box's M = 18.9 (p=.085).

Analysis revealed that there was no significant interaction of Agent and Liter flow for either mean maximum temperature (p=.896) or mean time to maximum temperature (p=.668). Additionally there was no significant main effect for Agent for either mean maximum temperature (p=.230) or mean time to maximum temperature (p=.863). The main effect for Liter flow was mixed. While there was no significant difference in mean time to maximum temperature by liter flow (p=.248), the 3 liter flow produced a consistently higher mean maximum temperature than the five liter flow overall (44.5 °C vs. 41.5°C, $p<.001$), and for both Isoflurane (44.8 vs. 41.8, p=.001) and Sevoflurane (44.2 vs. 41.1, p=.006). Complete results appear in Table 1. Research questions 5 and 6 asked if there were significant differences between the means of the six trials for the mean maximum temperature and the mean time to maximum temperature. This analysis effectively assessed if there were differences in temperature or time

based on the amount of hours the absorbent had been in use, with each trial representing an additional 2 hours of usage for a total of 12 hours of use for each canister.

Two-Way Analysis of Variance (ANOVA) was used to assess if there were significant differences in the mean maximum temperature and the mean time to maximum temperature for each of the six trial groups. The Levene's statistic was employed to test if the data met the homogeneity of variance assumption. While the variable *maximum temperature* met the assumption (Levene's p=.436) the variable *time to maximum temperature* did not (Levene's p=.002) and so the Brown-Forsythe correction was used in the analysis of the time variable.

The mean maximum temperature overall for all of the trial groups, was 43.1°C (SD=1.98°C) with a minimum of 42.2 °C and a maximum of 44.7 °C. The omnibus p for this test indicated that there was no significant difference in mean maximum temperature by trial (p=.343). The mean time to maximum temperature overall for all of the trial groups, was 107.7 minutes (SD=24.0 minutes) with a minimum of 80.3 minutes and a maximum of 118.8 minutes. The omnibus p test for these groups indicated that here was also no significant difference in mean time to maximum temperature by trial (p=.202). Complete results appear in Table 2.
The final research question 7, asked if one of the temperature probes (top, middle, bottom, outer) would register the maximum temperature a higher proportion of the time. A Chi-square Goodness of fit test was performed to compare the observed and expected frequencies for each probe to determine if each probe registered the maximum temperature in the equal proportion to the other probes. The middle probe registered the maximum temperature 19 of 23 times (82.6%) which was statistically significantly larger proportion of the time than the top probe which recorded the highest temperature 17.4% of the time, and the bottom and outer probes which never measured the highest temperature (X^2=9.783, df=1, p=.002). Interestingly, the top probe

only recoded the highest temperature under 3 liter flow conditions, under 5 liter flow the middle probe always registered the maximum temperature (X^2=4.439, df=1, p=.035). There were no significant differences by trial number (X^2= 5.59, df=5, p=.347) or agent (X^2=.009, df=1, p=.924). Complete results appear in Table 3.

Discussion

The Baralyme® samples were desiccated for 12 hours; replicating the time an anesthesia machine would go unchecked in a deployed setting. The initial weight of the four Baralyme® samples was 1217 grams and the moisture content was 11 percent (12). After 12 hours of exposure to 10 liters per minute of airflow, the weight changed to 1195.8 grams and a .2 percent dehydration of the four Baralyme® samples resulting in a moisture content of 10.8 percent.

No extreme heat production was observed in the 24 clinical simulated trials. Only trial 7, isoflurane 5 liter flow, had a temperature rise above 50 degrees Celsius (C). Trial 7, upon analysis, was deemed a multivariate outlier and excluded from further analysis, resulting in analysis of the remaining 23 trials.

The occurrence with trial 7 was a result of operator error. Carbon dioxide (CO_2) was allowed to build up in the artificial lung and the CO_2 canister prior to turning on the ventilator on. As a result, higher concentration of CO_2 was allowed to interact with the Baralyme® granules causing an accelerated chemical reaction resulting in higher initial temperatures of 50 C. Turning the ventilator on the Narkomed M anesthesia machine allowed the CO_2 to be flushed out of the CO_2 canister to the scavenging system, resulting in a decreased temperature within the CO_2 canister (15).

Attempts to answer research questions one, two, and four, revealed there were no clinical or statistical significant interaction of Agent and Liter flow for either mean maximum temperature or mean time to maximum temperature. This means that no matter which agent was used, sevoflurane or isoflurane, at either 3 liter or 5 liter flow, the time to reach maximum temperature was statistically insignificant. In research question three there was a statistical significance, but no clinical significance in the mean maximum temperature and amount of fresh gas flow between 3 liter and 5 liter flow. The overall mean maximum temperature was 44.5 C at 3 liters fresh gas flow and 41.5 C at 5 liters fresh gas flow.

The relationship between 3 liter and 5 liter flow in mean maximum temperatures can be explained by the increased in dilution of carbon dioxide and increased scavenging of carbon dioxide that occurs with 5 liter fresh gas flows. As a result, less CO_2 is available to enter the Baralyme® canister and subsequently less reaction takes place inside the CO_2 canister resulting

in decreased temperatures readings. Just the opposite occurs when lower flows are used, as in 3 liter flows, the concentration of CO_2 increases and less is scavenged, resulting in more contact with Baralyme® granules within the CO_2 canister producing higher temperatures readings. (16).

Research question five addressed the change in the maximum temperature between the six trials; and research question six addressed the significant change in the time to reach maximum temperature between the six trails. There were no statistical differences within each of the groups, sevoflurane and isoflurane at either fresh gas flow rates and between each group to reach maximum temperature. A possible explanation for these results can be attributed the amount of the Baralyme® that was dehydrated originally, .2%, leaving the Baralyme to react in a normal manner.

In answering research question seven; will one of the four temperature probes register the highest maximum temperature a larger proportion of the time than the others, the results showed the middle probe recorded the highest temperature 19 of 23 times (82.6%). The top probe recorded the highest temperature 17.4% of the time, but only when the flow was 3 liters. The bottom and outside probes never measured the highest. The location of the temperature probe on the absorber canister was statistically significant but had no clinical significance because of the non critical temperatures recorded.

The reasons why we believe that the Baralyme® reacted properly in recording consistently higher temperatures in the middle probe at the 5 liter flow rate is because of what is known about gas flow through the CO_2 canister. Channeling of non-homogenous flow of gas through the Baralyme granules can occur due to an improperly packed canister. Depending on the location of the channeling one would expect lower temperatures to occur because the gas

stream will follow the path of least resistance and little chemical reaction would occur, resulting in lower temperatures readings in that area of the canister (16).

The "wall effect" is a distinctive flow pattern along the smooth wall of the canister. This is due to the decreased resistance a smooth surface offers. As a result, there is less contact with the CO_2 absorbent and presumable increased gas flow rate. Temperature probes in areas affected by channeling or the "wall effect" would record lower than normal temperatures, indicated by less chemical reaction occurring. Knowing what affects gas flow through a CO_2 filled absorbent canister can also explain why at lower flows the top of the canister produced higher temperature. The reason is that more of chemical reactions occur at the top of the CO_2 canister because of decreased gas flow rate allowing more time for a chemical reaction to occur. If channeling and the "wall affect" did occur there would be more variability between each of the four temperature probes than what is reported (16).

Conclusions

The 23 clinical trials comparing sevoflurane and isoflurane when partially desiccated Baralyme® is used in the Narkomed M anesthesia at 3 liter and 5 liter fresh gas flow rates resulted in no clinical significance in maximum temperature recordings. The reason that no clinical significance occurred within the 23 trials is related to only .2% dehydration occurring in the Baralyme® after 12 hours of 10 liters per minute of air exposure. The limited desiccation that

occurred in this study is likely why our results differ from that found previously in the anesthesia literature.

Recommendation for a future study would include obtaining Baralyme® samples form the military deployment stock. Temperature testing should be conducted in a dry arid environment using clinically relevant liter flows. These recommendations would mimic a more realistic deployment setting to determine the safety of Baralyme®.

Table 1. Mean maximum temperature and time to mean maximum temperature by agent and liter flow

		3 liter (n=12)	5 liter (n=11)	**Overall** (N=23)
Maximum Temperature (mean °C)	Isoflurane (n=11)	44.8* (SD=1.5)	41.8* (SD=1.2)	**43.5** (SD=2.0)
	Sevoflurane (n=12)	44.2* (SD=1.2)	41.1* (SD=1.0)	**42.7** (SD=1.9)
	Overall (N=23)	**44.5*** (SD=1.3)	**41.5*** (SD=1.1)	**43.1** (SD=2.0)
Time to Maximum Temperature (mean minutes)	Isoflurane (n=11)	116.7 (SD=5.1)	99.8 (SD=31.2)	**109.0** (SD=21.9)
	Sevoflurane (n=12)	110.3 (SD=12.3)	102.5 (SD=37.1)	**106.4** (SD=26.7)
	Overall (N=23)	**113.5** (SD=9.6)	**101.3** (SD=32.9)	**107.7** (SD=24.0)

*$p<.01$ for comparison by liter flow, all other comparisons $p>.05$

Table 2. Mean maximum temperature and time to mean maximum temperature by trial

	Trial						
	1 (n=3)	2 (n=4)	3 (n=4)	4 (n=4)	5 (n=4)	6 (n=4)	Overall (N=23)
Maximum Temperature (mean °C)	**44.7** (SD=2.2)	**44.4** (SD=2.2)	**42.5** (SD=2.7)	**42.2** (SD=1.7)	**42.2** (SD=1.1)	**42.6** (SD=1.5)	**43.1** (SD=2.0)
Time to Maximum Temperature (mean minutes)	**80.3** (SD=47.9)	**111.8** (SD=8.0)	**94.8** (SD=35.1)	**117.3** (SD=1.7)	**118.8** (SD=1.5)	**116.3** (SD=3.3)	**107.7** (SD=24.0)

*All comparisons $p > .05$

Table 3. Probe measuring the highest temperature by liter flow and overall.

	Liter Flow		Overall
Probe	**3 liter**	**5 liter**	
Top	4 (33.3%)	0 (0%)•	4 (17.4%)
Middle	8 (66.6%)	11 (100%)	19 (82.6%)*
Bottom	0 (0%)	0 (0%)	0 (0%)
Outer	0 (0%)	0 (0%)	0 (0%)
	12 (100%)	11	12 (100%)

*p=.002 for overall proportion, •p=.035 for liter flow compared to other cellsData Analysis

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